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52835 7590 05/14/2010

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 05/14/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,975	04/28/2005	Yasumasa Mitani	20078.0005USWO	4649

TITLE OF INVENTION: PROCESS FOR AMPLIFYING NUCLEIC ACID

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/16/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

52835 7590 05/14/2010

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,975	04/28/2005	Yasumasa Mitani	20078.0005USWO	4649

TITLE OF INVENTION: PROCESS FOR AMPLIFYING NUCLEIC ACID

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/16/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
BERTAGNA, ANGELA MARIE	1637	435-091200

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/532,975	04/28/2005	Yasumasa Mitani	20078.0005USWO	4649
52835	7590	05/14/2010	EXAMINER	
HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			BERTAGNA, ANGELA MARIE	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 05/14/2010				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/532,975	MITANI ET AL.	
	Examiner	Art Unit	
	Angela M. Bertagna	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed on 1/29/2010.
2. ☒ The allowed claim(s) is/are 1-11 and 13-17.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>See Continuation Sheet</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|--|---|

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 07/15/2009; 08/26/2009; 10/20/2009; 03/03/2010; 03/15/2010; 04/13/2010.

DETAILED ACTION

Status of the Application

1. Applicant's response filed on January 29, 2010 is acknowledged. Claims 1-11 and 13-17 are currently pending. In the response, Applicant canceled claim 12.

As discussed below, Applicant's cancellation of claim 12, the arguments filed on January 29, 2010, and the evidence submitted under 37 CFR 1.132 on March 15, 2010 were sufficient to overcome all of the previously made rejections and objections, and, accordingly, they have been withdrawn.

Information Disclosure Statement

2. Applicant's submission of Information Disclosure Statements on August 26, 2009, October 20, 2009, March 3, 2010, March 15, 2010, and April 13, 2010 is acknowledged. Signed copies are enclosed.

It is noted that several non-patent literature references were not considered, because their citations do not comply with 37 CFR 1.98(b)(5), which requires a date of publication or public availability.

Also, non-patent literature reference #2 on the IDS filed on April 13, 2010 was not considered, because a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, has not been provided for this non-English language document as required by 37 CFR 1.98(a)(3).

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It is further noted that Applicant states in the response that non-patent literature documents 1, 2, and 8, which were cited on the IDS filed on July 15, 2009 and not considered previously, are from an invalidation trial proceedings and are not publications (page 7). Applicant argues that the citation of these documents on an IDS does not require inclusion of a date, and, therefore, these document should have been considered (page 7). This argument was not persuasive, because 37 CFR 1.98 makes clear that any non-patent literature information cited on an IDS must include a date (*i.e.*, a publication date or a public availability date). Since the citations of the non-patent literature documents do not include this information, the references have not been considered.

Finally, it is noted that the IDS filed on July 15, 2009 has been corrected to list the publication year of non-patent literature citation #6 (Mukai et al.).

Response to Amendment

3. The declaration under 37 CFR 1.132 filed March 15, 2010 is sufficient to overcome the rejection of claims 1-7 and 9-16 under 35 U.S.C. 103(a) as being unpatentable over Rabbani in view of Notomi and further in view of Nagamine and the rejection of claims 8 and 17 under 35 U.S.C. 103(a) as being unpatentable over Rabbani in view of Notomi and further in view of Nagamine and further in view of Kool. The evidence presented in the declaration filed on March 15, 2010, when considered with the evidence previously submitted and summarized in Applicant's response filed on January 29, 2010 (see pages 18-24), establishes that the use of primers having the claimed structural features results in unexpectedly improved amplification specificity and efficiency.

Response to Arguments

4. Applicant's arguments, see page 7, filed on January 29, 2010, regarding the objection to claim 12 have been fully considered and are persuasive. As noted by Applicant at page 7, the cancellation of claim 12 renders the previous objection moot, and, accordingly, it has been withdrawn.

Applicant's arguments, see pages 7-12 and 18-24, filed on January 29, 2010, regarding the rejection of claims 1-7 and 9-16 under 35 U.S.C. 103(a) as being unpatentable over Rabbani in view of Notomi and further in view of Nagamine, have been fully considered and are persuasive. As noted by Applicant at pages 7-9, the methods of Rabbani comprise a strand displacement mechanism that differs from the strand displacement mechanism of the methods of Notomi and Nagamine. Accordingly, the ordinary artisan would not have been motivated to combine the teachings of Notomi and Nagamine with those of Rabbani. Also, as noted by Applicant at pages 10-12, the evidence presented in the declaration filed on March 15, 2010, when considered with the evidence previously submitted and summarized in Applicant's response filed on January 29, 2010 (see pages 18-24), establishes that the use of primers having the claimed structural features results in unexpectedly improved amplification specificity and efficiency. Since Applicant's arguments were persuasive, the rejection has been withdrawn. The rejection of claims 8 and 17 under 35 U.S.C. 103(a) as being unpatentable over Rabbani in view of Notomi and further in view of Nagamine and further in view of Kool has also been withdrawn in view of the aforementioned arguments filed on January 29, 2010.

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EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Douglas Mueller (Reg. No. 30,300) on May 6, 2010.

The application has been amended as follows:

In the claims:

1. (currently amended) A process for synthesizing a nucleic acid complementary to a target nucleic acid sequence in a template nucleic acid, which comprises the steps of:

(a) annealing a primer to said template nucleic acid and synthesizing a complementary nucleic acid comprising the complementary sequence of said target nucleic acid sequence by a primer extension reaction,

wherein the primer comprises in its 3'-end portion a sequence (Ac') that hybridizes to a sequence (A) in the 3'-end portion of the target nucleic acid sequence, and in the 5'-side of said sequence (Ac'), a sequence (B') that hybridizes to the complementary sequence (Bc) of a sequence (B) positioned in the 5'-side of said sequence (A) on the target nucleic acid sequence,

wherein in the absence of an intervening sequence between said sequences (Ac') and (B'), X is in the range of 10 to 30, $(X-Y)/X$ is in the range of -1.00 to 0.75, and $(X+Y)$ is in the range of 30 to 50, in which X denotes the number of bases in said sequence (Ac'), and Y denotes the

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number of bases in a region flanked by said sequences (A) and (B) on the target nucleic acid sequence, and

wherein in the presence of an intervening sequence between said sequences (Ac') and (B'), X is in the range of 10 to 30, $\{X-(Y-Y')\}/X$ is in the range of -1.00 to 0.75, and $(X+Y+Y')$ is in the range of 30 to 50, in which X and Y have the same meanings as above, and Y' denotes the number of bases in said intervening sequence;

(b) hybridizing the sequence (B') positioned in the 5'-side of the complementary nucleic acid synthesized in step (a) with the sequence (Bc) on the same complementary nucleic acid, thereby allowing the portion of said sequence (A) on the template nucleic acid to be single-stranded, and

(c) annealing another primer having the same sequence as ~~said~~ the primer used in step (a) to the single-stranded sequence (A) portion of the template nucleic acid from step (b) and conducting a strand displacement reaction, thereby displacing the complementary nucleic acid synthesized in step (a) by the complementary nucleic acid newly synthesized with said another primer, and wherein steps (a), (b) and (c) are carried out in an isothermal condition.

9. (currently amended) A process for amplifying a target nucleic acid sequence in a double-stranded template nucleic acid, which comprises the steps of:

(a) annealing first and second primers to first and second template nucleic acids of a double-stranded template nucleic acid, respectively, and synthesizing first and second complementary nucleic acids comprising the complementary sequence of said target nucleic acid by a primer extension reaction, respectively,

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wherein the first primer comprises in its 3'-end portion a sequence (Ac') that hybridizes to a sequence (A) in the 3'-end portion of the target nucleic acid sequence in the first strand of the double-stranded template nucleic acid, and in the 5'-side of said sequence (Ac'), a sequence (B') that hybridizes to the complementary sequence (Bc) of a sequence (B) positioned in the 5'-side of said sequence (A) on said target nucleic acid sequence,

wherein in the absence of an intervening sequence between said sequences (Ac') and (B'), X is in the range of 10 to 30, $(X-Y)/X$ is in the range of -1.00 to 0.75, and $(X+Y)$ is in the range of 30 to 50, in which X denotes the number of bases in said sequence (Ac'), and Y denotes the number of bases in a first region flanked by said sequences (A) and (B) on the target nucleic acid sequence,

wherein in the presence of an intervening sequence between said sequences (Ac') and (B'), X is in the range of 10 to 30, $\{X-(Y-Y')\}/X$ is in the range of -1.00 to 0.75, and $(X+Y+Y')$ is in the range of 30 to 50, in which X and Y have the same meanings as above, and Y' denotes the number of bases in said intervening sequence,

wherein the second primer comprises in its 3'-end portion a sequence (Cc') that hybridizes to a sequence (C) in the 3'-end portion of the target nucleic acid sequence in the second strand of the double-stranded template nucleic acid, and in the 5'-side of said sequence (Cc') a sequence (D') that hybridizes to the complementary sequence (Dc) of a sequence (D) positioned in the 5'-side of said sequence (C) on said target nucleic acid sequence,

wherein in the absence of an intervening sequence between said sequences (Cc') and (D'), X is in the range of 10 to 30, $(X-Y)/X$ is in the range of -1.00 to 0.75, and $(X+Y)$ is in the range of 30 to 50, in which X denotes the number of bases in said sequence (Cc'), and Y denotes the

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number of bases in a second region flanked by said sequences (C) and (D) on the target nucleic acid sequence, and

wherein in the presence of an intervening sequence between said sequences (Cc') and (D'), X is in the range of 10 to 30, $\{X-(Y-Y')\}/X$ is in the range of -1.00 to 0.75, and $(X+Y+Y')$ is in the range of 30 to 50, in which X and Y have the same meanings as above, and Y' denotes the number of bases in said intervening sequence;

(b) hybridizing the sequences (B') and (D') positioned in the 5'-side of the first and second complementary nucleic acids synthesized in step (a) with the sequences (Bc) and (Dc) on the same complementary nucleic acid, respectively, ~~and thereby changing~~ converting the portions of said sequences (A) and (C) on the first and second template ~~nucleic acids into a single strand, respectively,~~ strands, respectively, to single-stranded form, and

(c) annealing additional primers having the same sequence as said primers used in step (a) to the single-stranded sequence (A) and (C) portions of the first and second template nucleic acids from step (b) and conducting a strand displacement reaction, thereby displacing the first and second complementary nucleic acid synthesized in step (a) by the complementary nucleic acids newly synthesized with said additional primers, and wherein steps (a), (b) and (c) are carried out in an isothermal condition.

Reasons for Allowance

6. The following is an examiner's statement of reasons for allowance: The instant claims are drawn to an isothermal nucleic acid amplification method that utilizes primers that have a 3' target-specific portion and a 5' portion that hybridizes to a portion of the extension product

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generated by polymerase-mediated extension of the primer to form a self-complementary portion that permits subsequent displacement of the extension product by an unextended primer having the same sequence. The claimed methods also impose particular length requirements on: (i) the 3'-target specific portion of the primers, (ii) the optional intervening sequence located between the 3' target-specific portion of the primers and the 5' portion of the primers, and (iii) the region flanked by the portions of the target nucleic acid that are targeted by the 3' and 5' portion of the primers.

The closest prior art is that of Rabbani et al. (EP 0 971 039 A2; cited previously), which teaches an isothermal amplification method that utilizes primers having a 3' target-specific portion and a 5' portion that hybridizes to a portion of the extension product generated by polymerase-mediated extension of the primer to form a self-complementary portion that permits subsequent displacement of the extension product by an unextended primer having the same sequence (see Figure 1 and Example 1). The primers utilized in the methods of Rabbani do not satisfy the additional structural requirements set forth in the instant claims 1 and 9, however. As discussed above, Applicant has demonstrated that the use of primers having the claimed structural features unexpectedly results in improved amplification specificity and efficiency. Accordingly, the claimed methods are novel and unobvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela M. Bertagna whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 9- 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Angela M Bertagna/
Examiner, Art Unit 1637